



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

March 4, 2019

Re: Animal Welfare Assurance  
#A3336-01 (OLAW Case 6I)

Dr. Lisa Cassis  
Vice President for Research  
University of Kentucky  
(b) (4) Main Building  
Lexington, KY 40506-0032

Dear Dr. Cassis,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 28, 2019 letters reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Kentucky, following up on an initial telephone report on February 25, 2019. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) A rat recovering from surgery was noted to be in distress. The animals had not been monitored as frequently as stated in the approved protocol.

Corrective actions: The laboratory staff was counseled on following the protocol, retrained on post-operative rodent care, and certified understanding of the content of the protocol.

- 2) Three mice died and one was moribund after being administered a seizure inducing drug and then not being monitored as frequently as stated in the approved protocol.

Corrective actions: All staff on the protocol was retrained on post-procedures care of mice, counseled on following the protocol, and certified understanding of the content of the protocol.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the Institutional Animal Care and Use Committee to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair  
Director, Division of Laboratory Animal Resources



**Office of the Vice President for Research**

311 Main Building  
Lexington, KY 40506-0032  
(859) 257-5294  
Fax: (859) 323-2800  
[www.research.uky.edu](http://www.research.uky.edu)

February 28, 2019

Axel Wolff, M.S., D.V.M.  
Deputy Directory  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Reference: Animal Welfare Assurance D16-00217 (A 3336-01)  
University of Kentucky

Dear Dr. Wolff:

The University of Kentucky Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, is reporting the following noncompliance and deviation from the *PHS Policy on the Humane Care and Use of Laboratory Animals* as required by section IV, F, 3a of the PHS Policy.

This incident was initially reported by telephone on February 26, 2019

On February 8, 2019, a Division of Laboratory Animal Resources (DLAR) employee noted that a rat that had undergone a surgical procedure was in distress. Review of documentation showed that the animals were monitored less frequently than described in the approved protocol.

In response to this noncompliance, the IACUC has required all members of the Principal Investigator's laboratory group to undergo retraining regarding post-operative care of rodents; and to document by signature that they have read and understand the current protocol. Further, the IACUC has communicated the expectation that all animal use adheres to that described in the approved protocol.

The IACUC believes that this action is an appropriate response to prevent similar future incidents. These studies were funded through a grant from the NIH Office of the Director (1R21OD018297-01A1) and National Institute of Neurological Disorders and Stroke (1R01NS101105-01).

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If you have questions concerning this incident, please contact Dr. Mark A. Suckow, Attending Veterinarian ([msuckow@uky.edu](mailto:msuckow@uky.edu); (b) (6)), Dr. M. Paul Murphy, IACUC Chair ([mpmurp3@uky.edu](mailto:mpmurp3@uky.edu); (b) (6)), or Dr. Lisa A. Cassis, Institutional Official ([lcassis@uky.edu](mailto:lcassis@uky.edu); (b) (6)).

Sincerely,

(b) (6)

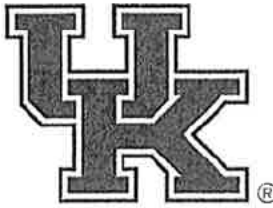
Lisa A. Cassis, Ph.D  
Vice President for Research  
Institutional Official

(b) (6)

M. Paul Murphy, Ph.D  
Chair, Institutional Animal Care  
and Use Committee

(b) (6)

Mark A. Suckow, DVM, DACLAM  
Attending Veterinarian



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February 28, 2019

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL1, Suite 360, MSC 7982  
6705 Rockledge Drive  
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Reference: Animal Welfare Assurance D16-00217 (A 3336-01)  
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Dear Dr. Wolff:

The University of Kentucky Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, is reporting the following noncompliance and deviation from the *PHS Policy on the Humane Care and Use of Laboratory Animals* as required by section IV, F, 3a of the PHS Policy.

This incident was initially reported by telephone on February 26, 2019.

On February 6, 2019, an investigator self-reported that mice that had been administered a compound to create a model of seizure had seemingly recovered after three days, but were then not monitored at the frequency described in the approved protocol. Subsequently, three mice were found dead and one was found to be weak and was euthanized.

In response to this noncompliance, the IACUC has required that all personnel listed as participants on the approved protocol undergo retraining within 30 days. This retraining will focus specifically on the post-procedure care to be given to mice. In addition, personnel have been instructed that they are expected to adhere to the approved protocol and to document by signature that they have read and understand the relevant protocol.

The IACUC believes that this action is an appropriate response to prevent similar future incidents. These studies were funded through a grant from the National Institute of Neurological Disorders and Stroke (2R44NS083218-03).

*An Equal Opportunity Employer*

If you have questions concerning this incident, please contact Dr. Mark A. Suckow, Attending Veterinarian ([msuckow@uky.edu](mailto:msuckow@uky.edu); (b) (6)), Dr. M. Paul Murphy, IACUC Chair ([mpmurp3@uky.edu](mailto:mpmurp3@uky.edu); (b) (6)), or Dr. Lisa A. Cassis, Institutional Official ([lcassis@uky.edu](mailto:lcassis@uky.edu); (b) (6)).

Sincerely,

(b) (6)

Lisa A. Cassis, Ph.D  
Vice President for Research  
Institutional Official

(b) (6)

M. Paul Murphy, Ph.D  
Chair, Institutional Animal Care  
and Use Committee

(b) (6)

Mark A. Suckow, DVM, DACLAM  
Attending Veterinarian

**Wolff, Axel (NIH/OD) [E]**

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**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Friday, March 1, 2019 10:15 AM  
**To:** 'Suckow, Mark'  
**Subject:** RE: Noncompliance Reports

Thank you for these reports, Dr. Suckow. I will send replies soon. In future, please send all final reports of noncompliance to [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

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**From:** Suckow, Mark <[msuckow@uky.edu](mailto:msuckow@uky.edu)>  
**Sent:** Friday, March 1, 2019 9:59 AM  
**To:** Wolff, Axel (NIH/OD) [E] <[wolffa@od.nih.gov](mailto:wolffa@od.nih.gov)>  
**Subject:** Noncompliance Reports

Dear Dr. Wolff,

Attached are two reports for recent noncompliance events at the University of Kentucky (A 3336-01). Please recall that we had discussed these by phone earlier this week. If these should be directed to someone else's attention, please let me know, and I am happy to do so.

Regards,

Mark A. Suckow, DVM, DACLAM

Associate Vice President for Research

Attending Veterinarian

Professor, Department of Biomedical Engineering

University of Kentucky

445 Bowman Hall

Lexington, KY 40506

(b) (6)



## Initial Report of Noncompliance

By: awDate: 2/25/19Time: 8:25Name of Person reporting: Mark SuckowTelephone #: (b)(6)

Fax #:

Email:

Name of Institution: U of KentuckyAssurance number: A3336Did incident involve PHS funded activity? yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

- 1) Mice died, not checked on weekly, not weighed. Epilepsy study - weren't watching endpoints
- 2) Mice not monitored + one got sick.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths: yes

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

1) Retrain.2) Enlarge mouse. Retrain

Projected submission to OLAW of final report from Institutional Official:

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Case # \_\_\_\_\_